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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,590	09/27/2001	Yung-Ming Chen	50623.00120	4003

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09/17/2002

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT

PAPER NUMBER

1734

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,590

Applicant(s)

CHEN ET AL.

Examiner

Laura E. Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 in Paper No. 3 is acknowledged.

Claim Rejections - 35 USC § 112

Claims 1-4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, "the application process" lacks antecedent basis.

In claim 3, it is unclear whether Applicants intend the coating substance to be a part of the claimed invention. If yes, it is suggested that Applicants recite --further comprising a source of coating substance including a polymer,... in fluid communication with the nozzle--.

In claim 4, it is unclear how the device intended to be coated being a stent further structurally limits the apparatus of claim 1.

In claim 8, it is unclear what is meant by a temperature modular? Do Applicants mean a --modulator-- or --module--?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leidner et al (US 6,056,993) in view of Kawata et al (US 4,932,353).

Leidner et al disclose coating methods including coating apparatus for manufacturing a stent comprising a nozzle or sprayer (39; see col. 14, lines 30-47) for providing [hot] melt coating material to a mandrel (12). Leidner et al are silent concerning the use of a temperature controller in thermal communication with the nozzle to adjust the temperature of the coating material during application. However, it was known in the coating art at the time the invention was made, to provide a temperature controller about a nozzle in order keep the temperature of the coating material constant and thereby control the viscosity or thickness of the coating material as it is being applied to a substrate such that uniform coating results on a substrate regardless of the peripheral temperature of the environment in which the coating is being performed as evidenced by Kawata et al (see col. 1, lines 35-41 and col. 3, lines 33-47). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Kawata et al about the Leidner et al nozzle in order to keep the temperature of the coating material constant and control the viscosity or thickness of the coating material as it is being

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applied to the mandrel such that uniform coating results on the mandrel regardless of the peripheral temperature of the environment in which the coating is being performed.

With respect to claim 5, while the apparatus as defined by the combination above is used in forming the stent and not to further coat a finished stent, it would have been obvious to one of ordinary skill in the art to use the same device for any further processing of the completed stent or other dried stents since removal of one stent for another on the mandrel would minimize costs and negate the need for a separate coating device.

With respect to claim 7, even though Leidner et al are silent concerning the sprayer being air assisted or atomized it would have been obvious to one of ordinary skill in the art to provide an atomizing sprayer in order to facilitate dispensing of the coating materials which can include volatile solvents.

With respect to claim 8, the apparatus as defined by the combination above is deemed to include a temperature modulator or constant temperature controller even though Kawata et al do not show one (see Kawata et al, col. 4, lines 46-50).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leidner et al (US 6,056,993) in view of Blackinton (US 4,132,357).

Leidner et al disclose coating methods including coating apparatus for manufacturing a stent comprising an electrostatic spray nozzle (10; see col. 5, lines 50-53) for providing coating material to a mandrel (12). Leidner et al are silent concerning the use of a temperature controller in thermal communication with the nozzle to adjust the temperature of the coating material during application. However, it was known in the coating art at the time the invention was made,

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to provide a temperature controller about an electrostatic nozzle in order keep the temperature of the coating material uniform and thereby control the viscosity or thickness of solvent based coating material as it is being applied to a substrate such that uniform coating results on a substrate regardless of the peripheral temperature of the environment in which the coating is being performed as evidenced by Blackinton (see col. 2, lines 47-66). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Blackinton about the Leidner et al nozzle in order to keep the temperature of the coating material uniform and control the viscosity or thickness of the coating material as it is being applied to the stent such that uniform coating results on the stent regardless of the temperature of the environment in which the coating is being performed.

With respect to claim 5, while the apparatus as defined by the combination above is used in forming the stent and not to further coat a finished stent, it would have been obvious to one of ordinary skill in the art to use the same device for any further processing of the completed stent or other dried stents since removal of one stent for another on the mandrel would minimize costs and negate the need for a separate coating device.

With respect to claim 7, even though Leidner et al are silent concerning the sprayer being air assisted or atomized it would have been obvious to one of ordinary skill in the art to provide an atomizing sprayer in order to facilitate dispensing of the coating materials which can include volatile solvents. Also, Blackinton recognizes the use of atomized sprayers to spray coating materials including volatile solvents (see col. 1, lines 10-14).

With respect to claim 8, the apparatus as defined by the combination above is deemed to include a temperature modulator or constant temperature controller as the heated air supplied to

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the shroud as taught by Blackinton is controlled via inlet conduit valving such that one of ordinary skill in the art would maintain uniform temperature via controlled valving inlets. See Blackinton col. 2, lines 66+ for controlled inlets.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (US 5,980,972) in view of Blackinton (US 4,132,357).

Ding teaches methods and apparatus for coating stents comprising an atomizer nozzle or sprayer (20) for applying a solvent based polymeric coating material to the stent, which is supported on a mandrel (24). Ding is silent concerning the use of a temperature controller in thermal communication with the air-assisted nozzle to adjust the temperature of the coating material during application. However, it was known in the coating art at the time the invention was made, to provide a temperature controller about a nozzle in order keep the temperature of the coating material uniform and thereby control the viscosity or thickness of solvent based coating material as it is being applied to a substrate such that uniform coating results on a substrate regardless of the peripheral temperature of the environment in which the coating is being performed as evidenced by Blackinton (see col. 2, lines 47-66). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Blackinton about the Ding nozzle in order to keep the temperature of the coating material uniform and control the viscosity or thickness of the coating material as it is being applied to the stent such that uniform coating results on the stent regardless of the temperature of the environment in which the coating is being performed.

With respect to claim 7, see Ding, col. 6, lines 1-5.

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With respect to claim 8, the apparatus as defined by the combination above is deemed to include a temperature modulator or constant temperature controller as the heated air supplied to the shroud as taught by Blackinton is controlled via inlet conduit valving such that one of ordinary skill in the art would maintain uniform temperature via controlled valving inlets. See Blackinton col. 2, lines 66+ for controlled inlets.

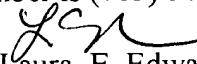
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following publication discloses the state of the art with respect to coating stents: WO01/52772.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura E. Edwards whose telephone number is (703) 308-4252. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (703) 308-3853. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7115 for regular communications and Same as above for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Laura E. Edwards
Primary Examiner
Art Unit 1734

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September 13, 2002